

REMARKS

Claims 1, 2, 40, 42, 43, 45-49, 51, 52, and 81-88 were presented for examination and were rejected in the *Final Office Action* of September 7, 2011 (hereinafter "Office Action").

Without conceding to the merits of the rejections issued in the Office Action, the applicants have amended independent claim 1 to advance the prosecution of the instant application. Additionally, claim 2 has been amended to conform to U.S. patent practice, and claim 42 has been amended to depend on claim 1.

The applicants respectfully request reconsideration in light of the foregoing amendments and the following comments.

Telephone Interview

A telephone interview was conducted between the applicants' undersigned representative and Examiner Wood on December 8, 2011.

In general, the telephone interview was to discuss the obviousness rejection based on US Patent Application Publication No. 2003/0120257 (hereinafter "*Houston '257*"), US Patent Application Publication No. 2004/0037986 (hereinafter "*Houston '986*"), and US Patent No. 5,556,426 (hereinafter "*Popadiuk*").

During the telephone interview, the undersigned respectfully directed the Examiner's attention to page 3 and page 7 of the Office action, and indicated that the Examiner's statements made at these pages are in conflict with one another.

More specifically, the undersigned indicated that page 3 of the Office Action states that Houston '257 and Houston '986" are silent with regard to an "*external helical formation*," but page 7 of the Office Action states that Houston '257 or Houston '986" discloses an "*external helical formation*."

Although the Examiner agreed that the statements made at page 3 and page 7 of the Office Action are in conflict, no agreements were reached during the telephone interview to advance the prosecution of the instant application.

35 USC § 103 Rejection of Claims 1, 2, 40, 42, 43, 45-49, 52, and 81-86

Claims 1, 2, 40, 42, 43, 45-49, 52, and 81-86 were rejected under 35 USC § 103 as being obvious over the combination of Houston '257, Houston '986, and Popadiuk.

As discussed above, independent claim 1 has been amended to advance the prosecution of the instant application. The applicants respectfully submit that the rejection is overcome in light of the foregoing amendment and for at least the reasons discussed below.

Independent claim 1, as amended, recites:

1. A tubular conduit comprising:

a tubular portion comprising an inside and an outside and being made from a flexible material;

an axially extending external helical formation located around the outside of the tubular portion for supporting the tubular portion; and

an axially extending internal helical protrusion located around the inside of the tubular portion for imparting a helical flow to a fluid passing through the tubular portion, having a different helix angle from the external helical formation;

wherein the axially extending internal helical protrusion comprises a section of the tubular portion deformed by an axially extending deformation helix; and

wherein the external helical formation and the axially extending deformation helix are made from the same material; and

wherein an outer surface of the axially extending deformation helix is substantially flush with the outside of the tubular portion.

(emphasis supplied)

First: The present invention, as defined by the claims, pertains to a tubular conduit. In one embodiment, a blank vascular graft (1) is fitted on to a mandrel (3). The mandrel (3), with the vascular graft (1) on it, is placed within two semi-circular channels (7,9) in mould blocks (5, 6) such that an injection hole formed by injection channels (12, 13) is aligned with helical channel (4). The two mould blocks (5, 6) are then held tightly together, for example, by retaining screws to form mould (2). (*published specification at ¶67 and ¶68*).

The mould (2), together with the vascular graft (1), is placed in a pressurizable injection moulding machine. Molten polyurethane is then injected via the injection hole formed by injection channels (12, 13) into the interior of mould (2). (*published specification at ¶71*).

The molten polyurethane deforms the vascular graft (1) by pressing it into a helical channel (4) of the mandrel (3) to create a helical protrusion (15) on the inside surface of the vascular graft (1). It simultaneously creates a "*helical groove*" on the outside surface of the vascular graft (1) into which molten polyurethane flows. (*published specification at ¶71*).

The molten polyurethane also flows along the helical channel formed by the grooves (11) of the mould (2). Thus, only a *single* injection of molten polyurethane is required to fill both the "*helical groove*" of vascular graft (1) and the "*helical channel*" of mould blocks (5, 6). (*published specification at ¶72*).

Based on this single injection moulding process, a polyurethane deformation helix (16) is created, whose outer surface lies substantially flush with the outer surface of the vascular graft (1), and which deforms the vascular graft (1) so as to provide an internal helical protrusion (15). The single injection moulding process simultaneously creates a support helix (17), which winds around the exterior of the vascular graft (1) and sits slight proud of the rest of the outer surface of the vascular graft (1). (*published specification at ¶73*).

As further discussed below, these features of the claimed invention, however, are neither taught nor suggested by the cited references, whether considered individually or in any combination.

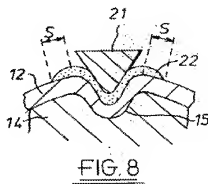
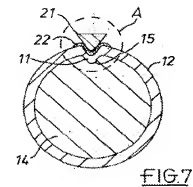
Second: According to the Office Action, the Office interprets the "*helical groove (15)*" disclosed in Houston '257 as corresponding to the "*axially extending deformation helix*" recited in claim 1.

Without conceding to the correctness of the Office's interpretation and rejection, claim 1 has been amended to recite that "*an outer surface of the axially extending deformation helix is substantially flush with the outside of the tubular portion.*" (*published specification at ¶73*).

The applicants respectfully submit that a conduit having this feature is more structurally sound and less likely to kink compared with a device having an external groove.

In contrast to the limitation at issue, Houston '257 discloses that *"the penetration of the polyurethane 22 into the material 12 will be approximately 80% to 90% of the thickness of the material 12."* (Houston '257 at ¶34).

An enlarged view of the helical groove (15) after applying the polyurethane dispersion (22) is illustrated in Figure 7 and Figure 8 of Houston '257, as reproduced below:



As clearly depicted in the above figures from Houston '257, the polyurethane dispersion (22) that is applied to the helical groove (15) is not substantially flush with the outer surface of tubular material (12). The reason that the helical groove (15) of Houston '257 continues to have an indentation, groove, etc. is because former (21) is used to press the polyurethane dispersion (22) into the tubular material (12). (Houston '257 at ¶34). As a consequence, Houston '257 cannot teach, suggest, or motivate the limitation at issue recited in amend claim 1.

With respect to the secondary references of Houston '986 and Popadiuk, these references likewise fail to teach, suggest, or motivate the limitation of "[a] tubular conduit ... wherein an outer surface of the axially extending deformation helix is substantially flush with the outside of the tubular portion."

Accordingly, the combination of Houston '257, Houston '986, and Popadiuk fails to obviate amended claim 1. Accordingly, amended claim 1 is allowable over the art of record.

Third: The applicants argued in the *Response* filed on June 17, 2011 that Houston '257, Houston '986, and Popadiuk fail to teach, suggest, or motivate the limitation of "[a] tubular conduit ... wherein the external helical formation and the axially extending deformation helix are made from the same material." (published specification at ¶72).

The applicants respectfully maintain this argument and request that the Office reconsider the rejection based on the following comments.

As disclosed and claimed by the applicants, the tubular conduit (1) is created by using a single injection of molten polyurethane into moulding blocks (5, 6). This single injection moulding process simultaneously produces the deformation helix (16) and external helical formation (17). Following this process leads to a tubular conduit (1) with both helical formations (16, 17) made from the same material. (*published specification at ¶71, ¶72, and ¶82*).

According to the Office Action, the Office interprets the "*helical groove (15)*" applied with a "*polyurethane dispersion (22)*" of Houston '257 as corresponding to the limitation of an "*axially extending deformation helix*" recited in amended claim 1.

Further, the Office interprets the "*filament component (14)*" made from "*poly-tetra-fluoro-ethylene (PTFE)*" of Popadiuk as corresponding to the limitation of an "*axially extending external helical formation*" recited in amended claim 1.

However, the Office's combination of Houston '257 and Popadiuk would ultimately result in a deformation helix that is made from polyurethane and an external helix that is made from PTFE — i.e., different materials.

This conclusion is supported by Houston '257 disclosure that "[a]fter forming of the helical formation 11, a polyurethane dispersion 22 is applied" (Houston '257 at ¶34), and Popadiuk's disclosure that "*the filament component and the tubing component are manufactured from the same fluoropolymer, most preferably PTFE.*" (Popadiuk at col. 6, ll. 47-49).

As is well known and well-understood by a person skilled in the art, polyurethane and PTFE are different plastics, with very different physical properties. Thus, the Office's combination of Houston '257 and Popadiuk does not teach, suggest, or motivate the limitation of "*wherein the external helical formation and the axially extending deformation helix are made from the same material*" recited in amended claim 1.

For all the reasons discussed above, amended claim 1 is allowable over Houston '257, Houston '986, and Popadiuk, whether considered individually or in any combination.

Since claims 2, 40, 42, 43, 45-49, 52, and 81-86 depend on amended claim 1, and because amended claim 1 is believed to be allowable for the reasons presented, these dependent claims are likewise allowable. Moreover, the recitation of additional patentable features recited in these dependent claims provides an additional basis for their patentability.

35 USC § 103 Rejection of Claim 51

Claim 51 was rejected under 35 USC § 103 as being obvious over the combination of Houston '257, Houston '986, Popadiuk, and US Patent No. 5,827,327 (hereinafter "*McHaney*"). The applicants respectfully submit that the rejection of claim 51 is overcome for at least the reasons discussed below.

With respect to amended claim 1, the secondary reference of *McHaney* fails to cure the deficiencies of Houston '257, Houston '986, and Popadiuk discussed above. As a consequence, the art of record, whether considered individually or in any combination, fails to anticipate or obviate amended claim 1.

Since claim 51 depends on amended claim 1, and because amended claim 1 is believed to be allowable for the reasons presented, this dependent claim is likewise allowable. Moreover, the recitation of additional patentable features recited in this dependent claim provides an additional basis for its patentability.

No Waiver

All of the applicants' arguments are without prejudice or disclaimer. The applicants reserve the right to discuss the distinctions between the applied art and the claims in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Office, the applicants do not acquiesce to the Office's additional statements. The distinctions discussed by the applicants above are sufficient to overcome the rejections.

Request for Reconsideration Pursuant to 37 CFR § 1.111

Having responded to each and every ground for objection and rejection in the last Office action, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR § 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' attorney so that those issues can be resolved as quickly as possible.

Respectfully,
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